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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,877	03/05/2002	Philip T. Feldsine	150026.457C1	7854

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/091,877	<b>Applicant(s)</b> FELDSINE ET AL.	
	<b>Examiner</b> Ulrike Winkler	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*HL*

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2004 has been entered.

#### *Specification*

The Office acknowledges the amendments to the title of the specification.

#### *Claim Rejections - 35 USC § 102*

The rejection of claims 1, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Deng et al. (Antimicrobial Agents and Chemotherapy, 1995) **is withdrawn** in view of applicants' amendments to the claims.

#### *Claim Rejections - 35 USC § 103*

The rejection of claims 1, 3, 4 and 27 under 35 U.S.C. 103(a) as being unpatentable over Deng et al. (Antimicrobial Agents and Chemotherapy, 1995), Marino et al. (Journal of Bacteriology 1991, see IDS) and Ohyama et al. (Journal of Bacteriology 1992, see IDS) **is maintained** for reasons of record. The rejection is evidenced by the Handbook: Microbiological Media (Ronald M., 1997, CRC Press Inc. Boca Raton, FL, pp 1113, 1349, 1482, 1491, 1492).

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Applicants' arguments have been fully considered but fail to persuade. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Deng et al. incubated mycobacteria in the presence of Tween and a structure modifying organic compound, the reference specifically looked at the effects on the cell wall composition, indicating that the bacterial cell wall is modified. The use of detergents such as Tween in bacterial cell culture is well known (see Ronald M., Handbook: microbiological media pp 1113, 1349, 1482, 1491, 1492), Tween not only acts to prevent cell clumping but it can also act as an additional energy source for some bacteria. Marino et al. treated cells with DNP and observed the changes in the cell wall composition, indicating that the structure of the bacterial cell wall has been modified. So both the Deng et al. reference and the Marino et al. reference provide bacterial incubation methods that alters the structure of the cell wall. The ordinary artisan would recognize that alteration of a bacterial cell wall would have an effect on the antigenicity of the cell. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In response to applicant's argument that the composition "permitting multiplication to optimal levels for detection," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The intended use of achieving optimum growth levels for detection would not effect the composition.

The instant invention is drawn to a composition comprising a general enrichment media including a detergent and at least one structure modifying organic chemical, and a method of propagating the microorganism. Wherein the structure modifying compound is selected from 2,4-dinitrophenol (DNP) or carbonyl cyanide-m-chlorophenyl hydrazone.

Deng et al. teaches the culturing of *Mycobacterium smegmatis* in glycol-alanine-salts medium in the presence of Tween 80 and ethambutol, a structure modifying compound (see page 696, paragraph spanning column 1 and 2). The use of Tween in the growth medium is to prevent clumping of the microorganism. The reference does not disclose incubating the microorganism using 2,4-dinitrophenol (DNP) or carbonyl cyanide-m-chlorophenyl hydrazone.

Marino et al. teach incubating microorganism in growth medium (PPBE) and 1 mM 2,4-dinitrophenol (DNP). The reference also looks at the change in LPS location after incubation with DNP (see figure 3, and table 1). The reference also looks at the translocation of LPS in the presence of CCCP (see table 2).

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Ohyama et al. teach incubating microorganism in growth medium in the presence of carbonyl cyanide-m-chlorophenyl hydrazone (CCCP).

It would have been obvious to one of ordinary skill in the art to add a detergent to the growth medium comprising a microorganism in order to avoid the clumping of the microorganism as set out in Deng et al. The use of detergents such as Tween in bacterial cell is well known (see Ronald M., Handbook: microbiological media pp 1113, 1349, 1482, 1491, 1492), Tween not only acts to prevent cell clumping but it can also act as an additional energy source for some bacteria. One having ordinary skill in the art would have had a high expectation of success in adding the detergent to the procedures set out in Ohyama et al. or Marino et al. Therefore, the instant invention would have been obvious over Deng et al., Marino et al. and Ohyama et al.

### *Conclusion*

No claims allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

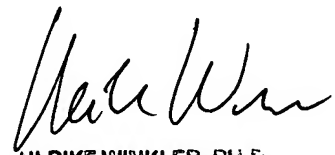
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

  
ULRIKE WINKLER, PH.D.  
PRIMARY EXAMINER 4/4/05